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A Dreadful Prognosis: Patentability of Diagnostic and Personalized Medical Procedures in the Wake of *In re Bilski*

by MATTHEW D. SHOW, PH.D.*

“If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea” —Thomas Jefferson¹

I. Introduction

The Constitution grants Congress sweeping authority to define patentable subject matter. However, the section of the modern Patent Act describing precisely what qualifies as a patentable invention is essentially identical to the language penned by Thomas Jefferson when he wrote the first Patent Act at the end of the 18th Century. Given the incredible advances in science, medicine, and engineering over the last two and a quarter centuries, the fact that most inventions still fall into what Jefferson considered “patentable subject matter” is a testament to his vision and foresight. However, over the past few decades, patent applicants in certain technological fields are discovering a conflict inherent between the nature of their claimed inventions and judicial interpretation of Jefferson’s Patent Act language throughout the 19th and 20th Centuries.

This conflict is particularly apparent in the fields of diagnostic and personalized medicine. Diagnostics is an ancient branch of medicine focusing on the identification of a disease or other abnormal condition from the symptoms a patient presents to a diagnostician. By recognizing the basic biochemical and physiological signs of a

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1. VI THE WRITINGS OF THOMAS JEFFERSON, at 180–81 (Henry A. Washington ed., 1871).

pathological state, a physician is able to determine what course of treatment is required to return the patient to health. Personalized medicine, on the other hand, is a much newer concept. Essentially, it is the application of information gleaned from the Human Genome Project and other large-scale genetic studies of inherited disease to individuals susceptible to these conditions due to inheritance or mutations in their DNA. The goal of personalized medicine is to use an individual's unique genetic "code" to predict what medical conditions that person may be susceptible to during their life and to determine what form of treatment will best alleviate or even prevent manifestation of that medical condition.

This Note will review the development and the interpretation of the patentable subject matter section of the Patent Act, 35 U.S.C. § 101, as applied to diagnostic and personalized medicine method patents from the time of Jefferson to the present day. Modern Supreme Court precedent concerning what exactly qualifies as a patentable method claim will be discussed as well as how a business method case, *Bilski v. Kappos*, threatens to make these types of methods unpatentable. Additionally, the results of an analysis demonstrating how patent agents and attorneys currently draft these types of claims will be presented along with information as to how to alter these claims to conform to the en banc Federal Circuit's decision in *Bilski*. Finally, this Note will argue these types of method claims are not only deserving of patentability, they are a vital part of the American economy and are critical for the maintenance and improvement of public health.

II. Background: The Contentious History of Medical and Diagnostic Method Patents

A. A Brief Overview of United States Patent Law

The Constitution delegates to Congress the authority "[t]o promote the progress of science and useful arts, by securing for limited times to... inventors the exclusive right to their... discoveries."² Congress implements this authority in Title 35 of the United States Code, which details the broad requirements for obtaining a United States patent.³ At the heart of the patent system is a fundamental quid pro quo between the inventor and society: the

2. U.S. CONST. art. I, § 8, cl. 8.

3. 35 U.S.C. (2006).

inventor agrees to disclose the details of her invention to the public in exchange for a temporally-limited “right to exclude others from making, using, offering for sale or selling the invention throughout the United States or importing the invention into the United States”⁴ The means of this disclosure is through the filing and successful prosecution of a patent application with the U.S. Patent and Trademark Office (PTO).⁵

In order to be patentable, an invention must pass several hurdles during the application and prosecution process. A patent applicant must satisfy a PTO Examiner that the subject matter of the invention described in the application is both novel⁶ and nonobvious.⁷ These requirements ensure the monopoly granted to the inventor is not already available to the public nor is obvious to one of ordinary skill in the relevant art given what is known in that art at the time of the alleged discovery. As a result, the novelty and obviousness requirements prevent ideas already in the public domain from becoming inaccessible by the granting of a patent.

Additionally, an applicant must fully describe his invention such that one having ordinary skill in the art to which the invention pertains can make and use the invention.⁸ This includes revealing to the public the best mode of utilizing the invention so that once the patent expires, the public may fully employ it for their benefit.⁹ The patent application concludes with a number of claims, which must distinctly point out and describe exactly what the inventor is claiming as her invention.¹⁰ This serves the dual function of informing the PTO of the metes and bounds of the patent applicant’s claimed property right as well as putting the public on notice as to the existence of the claimed invention.

Not all discoveries are patentable. Usually, the first consideration during prosecution is whether the invention described in the application falls within one of four classifications Congress deems

4. 35 U.S.C. § 154(a)(1) (2006).

5. Prosecution of patent applications is governed by 37 C.F.R. (2007) while PTO rules controlling examination of applications are found in the Manual of Patent Examining Procedure (MPEP), U.S. Patent and Trademark Office, Manual of Patent Examining Procedure (8th ed. 2001, rev. Jul. 2008).

6. 35 U.S.C. § 102 (2006).

7. *Id.* § 103 (2006).

8. *Id.* § 112, ¶ 1 (2006).

9. *Id.*

10. *Id.* § 112, ¶ 2 (2006).

appropriate subject matter for a patent.¹¹ The Supreme Court has interpreted this section of the patent code very broadly, going as far as declaring that patentable subject matter extends to “anything under the sun made by man.”¹² As detailed, *infra*, this section of the patent code has remained extraordinarily stable for more than two centuries despite the rapid changes occurring in the fields of science and engineering during the Industrial Revolution and the later advances of the Computer and Space Ages.

B. The Genesis of 'Patentable Subject Matter' in 35 U.S.C. §101

At first glance, it may seem odd that Thomas Jefferson would come to author the first United States Patent Act.¹³ To Jefferson, a leading intellectual of the Enlightenment and a prominent inventor himself, the proposition that the fruit of man’s inventive genius could somehow be “owned” suggested a heresy to a natural order “peculiarly and benevolently designed by nature.”¹⁴ Nevertheless, taking his lead from the English Statute of Monopolies,¹⁵ Jefferson wrote the Patent Act of 1790 sanctioning patents for “any useful art, manufacture, engine, machine, or device, or any improvement therein”¹⁶ to encourage “men to pursue ideas which may produce utility.”¹⁷ Congress amended the Act in 1793 to permit the patenting of “any art, machine, manufacture, or composition of matter, or any new and useful improvement [thereof]”¹⁸ and again in 1952 when the word “art” was changed to “process.”¹⁹ Remarkably, aside from these minor changes, the patentable subject matter section of the modern Patent Act, Title 35, § 101 of the United States Code, remains identical to the words Jefferson penned over two centuries ago. The subject matter of all patents issued in the United States must be capable of classification as a “process, machine, manufacture, or composition of matter.”²⁰

11. 35 U.S.C. § 101 (2006).

12. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

13. Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109.

14. THE WRITINGS OF THOMAS JEFFERSON, *supra* note 2 at 180–81.

15. English Statute of Monopolies, 1623, 21 Jac. 1, c. 3, § 6.

16. Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109.

17. THE WRITINGS OF THOMAS JEFFERSON, *supra* note 2 at 180–81.

18. Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318.

19. 35 U.S.C. § 101 (2006).

20. *Id.*

Medical and biological knowledge in the late 18th Century was still medieval by today's standards. Diagnoses of maladies based on the ancient beliefs of "humors" and other superstitions were common.²¹ The practice of "bleeding" those suffering from diseases with leeches to restore "balance" to the humors was particularly in vogue during Jefferson's time.²² Surgery was primitive, with the concepts of sterilization, anesthetic, and even basic knowledge of human anatomy decades to a century away. Jefferson was well acquainted with the limitations of medical science, having mourned the deaths of four infant children and his young wife following years of illness, in spite of the availability of the best doctors in colonial America at the time.²³ With this backdrop in mind and English precedent to guide him, Jefferson chose the subject matter that would qualify as patentable under the United States' new system. Therefore, it is of little wonder that this regime was initially hesitant to permit patent grants claiming medical, surgical, and diagnostic methods.

C. Early case law held scientific principles as well as medical and surgical methods were not patentable subject matter

From the beginning, both the Patent Office as well as the courts refused to extend patentable subject matter to include discoveries of scientific principles.²⁴ Specifically, the Supreme Court has held:

"[L]aws of nature, physical phenomena, and abstract ideas [are] not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."²⁵

Perhaps the most famous instance of an inventor attempting to capture a scientific principle occurred in the so-called "Telegraph

21. David Keirse, PLEASE UNDERSTAND ME II: TEMPERAMENT, CHARACTER, INTELLIGENCE 23 (Prometheus Nemesis 1998).

22. Gilbert Seigworth, *Bloodletting Over the Centuries*, 80 N.Y. ST. J. MEDICINE 2022 (1980).

23. Biography of Martha Wayles Skelton Jefferson, http://www.whitehouse.gov/about/first_ladies/marthajefferson/ (last visited Oct. 12, 2009).

24. 1 Donald S. Chisum, *Chisum on Patents* § 1.03[2] (2003).

25. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948))(internal citation omitted).

Case,” where the Supreme Court invalidated a claim in Samuel Morse’s patent for the telegraph.²⁶ Morse’s eighth claim incorporated all uses of the principle of electromagnetism for the communication of written characters over distances.²⁷ The Court noted that “some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification” and therefore require Morse’s permission for its use.²⁸ Thus, the Court found the claim would preempt any and all use of the natural phenomenon of electromagnetism for the conveyance of messages and was therefore invalid for claiming unpatentable subject matter.²⁹

Similarly, in one of the first cases to examine the patentability of a medical procedure, the New York Circuit Court ruled doctors who discovered that inhalation of ether would render a patient unconscious prior to surgery could not patent a method employing that innovation.³⁰ While the opinion in *Morton v. New York Eye Infirmary* characterized the inventors as having made one of the “great discoveries of modern times,”³¹ the Court nevertheless cast doubt on the patentability of medical procedures in general. The court noted that a “discovery may be brilliant and useful, and not patentable. No matter through what long, solitary vigils . . . the secret may have been wrung from the bosom of Nature . . . Something more is necessary.”³² The Court went on to remark that “[n]either *the natural functions of an animal upon which or through which [a combination] may be designed to operate*, nor any of the useful purposes to which it may be applied” could form parts of the patented combination.³³ The natural process of inhaling a gas, even if the result

26. O’Reilly v. Morse, 56 U.S. 62 (1854).

27. *Id.* at 112; Morse’s eighth claim: “I do not propose to limit myself to the specific machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letter, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.”

28. *Id.* at 113.

29. *Id.*

30. *Morton v. N.Y. Eye Infirmary*, 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9865).

31. *Id.* at 883.

32. *Id.* at 884.

33. *Id.* (emphasis added).

of that process brought about a revolution in surgery and medicine, did not qualify for the protection of a patent grant.

Following *Morton*, courts and the Patent Office used the language of its holding to prevent the patenting of medical methods for treating the human body in general.³⁴ In *Ex parte Brinkerhoff*,³⁵ the Patent Office relied on *Morton* to conclude the applicant's method of using medical instruments to treat hemorrhoids was not patentable subject matter. In formulating an almost *per se* rule, the Commissioner of Patents declared "methods or modes of treatment of physicians of certain diseases are not patentable."³⁶ However, as medical science and technology slowly advanced, later decisions by U.S. District Courts and the Patent Office Board of Appeals began to back away from this ostensibly automatic rule.³⁷ For example, in *Dick v. Lederle Antitoxin Laboratories*, a district court determined a skin test for revealing the vulnerability of a person to Scarlatina was patentable subject matter.³⁸

Eventually, seventy-one years after the fact, the Patent Office Board of Appeals overruled *Ex parte Brinkerhoff*'s prohibition against the patenting of all medical method patents.³⁹ This decision opened the door for the relatively recent phenomenon of patents directed to methods of practicing surgical, diagnostic, and personalized medicine. The reason why the law developed in this manner is unclear. It is certainly plausible that by the middle of the 20th Century, medical science had advanced so far from the time of Jefferson that methods directed to the treatment of disease were reliable and consistently reproducible. Advances in basic science, the development of vaccines for common diseases, the discoveries of antibiotics and the principles of the genetic basis of inheritance certainly supports this notion. Alternatively, seeing the incredible progress of medical science, the PTO and the courts may have determined it was in the public interest to have the patent system incentivize the development of even greater medical advances.

34. 1-1 Donald S. Chisum, *Chisum on Patents* § 1.03[3] (2010).

35. *Methods or Modes of Treatment of Diseases--Held Unpatentable*, *Ex parte Brinkerhoff*, 27 J. Pat. Off. Soc'y 797 (1945).

36. *Id.* at 798.

37. Chisum, *supra* note 35, §1.03[3]; *Ex parte Kettering*, 35 U.S.P.Q. 342 (Pat. Off. Bd. App. 1936); *Ex parte Wappler*, 26 U.S.P.Q. 191 (Pat. Off. Bd. App. 1934); *see also* *Becton-Dickinson v. Scherer*, 106 F. Supp. 665 (E.D. Mich. 1952), *aff'd*, 211 F.2d 835 (6th Cir. 1954); *Ellis v. Coe*, 49 U.S.P.Q. 232 (D. D.C. 1941).

38. *Dick v. Lederle Antitoxin Labs.*, 43 F.2d 628 (S.D. N.Y. 1930).

39. *Ex parte Scherer*, 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

Whatever the reason, as science advanced, patent applicants, the PTO, and the courts again faced the ghosts of *Morse*, *Morton*, and *Brinkerhoff* as they attempted to fit claims to the seemingly natural principles of diagnostic and personalized medicine into the language of 35 U.S.C. §101. The problem of how diagnostic methods fit into the traditional categories of patentable subject matter would come to a head in 2006. The results would be satisfying to very few.

D. *Laboratory Corp. v. Metabolite*: The Supreme Court Decides It Would Be A Good Idea To Not Decide

Lab. Corp. concerned the validity of a patent claiming a method for the diagnosis of certain diseases caused by dietary deficiencies of vitamin B12 and folate.⁴⁰ Humans need these vitamins to ensure the proper synthesis of amino acids, which are the building blocks of proteins, as well as for the production of the nucleic acids DNA and RNA.⁴¹ Vitamin B12 and folate deficiencies are associated with improper DNA methylation and subsequent impaired DNA biosynthesis, pernicious anemia, increased risks for cardiovascular disease and adverse pregnancy outcomes, as well as neural tube defects such as spina bifida.⁴² The inventors, who assigned the patent to a company that eventually granted a license to Metabolite, discovered that people suffering from medical conditions associated with B12 and folate deficiencies have high levels of a certain amino acid, homocysteine, present within their blood serum.⁴³ Careful measurement of the relative concentration of this factor when compared to normal serum homocysteine levels could diagnosis the presence of a B12 or folate deficiency in patients suffering from diseases associated with this condition.⁴⁴

Metabolite sued LabCorp., a former licensee, for inducing others to infringe its patent when LabCorp. began using another company's test for determining serum levels of homocysteine.⁴⁵ Rather than assert LabCorp.'s use of the rival company's test infringed the patent's claims for measuring homocysteine in serum, Metabolite

40. U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

41. Donald & Judith Voet, *Biochemistry* 675 (2d ed. 1995).

42. G. Moreiras et al., *Cobalamin, Folic Acid, and Homocysteine*, 67 Suppl 1. Nutr Rev. S69 (2009).

43. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 128 (2006) (Breyer, J., dissenting).

44. *Id.*

45. *Id.* at 129 (Breyer, J., dissenting).

chose to assert the much broader claim 13,⁴⁶ arguing it “created a protected monopoly over the process of ‘correlating’ test results and potential vitamin deficiencies.”⁴⁷ At trial, a jury agreed with Metabolite and found LabCorp. induced others to infringe this very broadly construed claim.⁴⁸ Essentially, by providing test results of serum homocysteine levels to doctors, LabCorp. induced the doctors who ordered those tests to infringe claim 13 simply through the act of examining the test results and correlating those results with the presence or absence of a B12 or folate deficiency.⁴⁹ On appeal, the Court of Appeals for the Federal Circuit affirmed the jury decision,⁵⁰ rejecting LabCorp.’s contention that if Metabolite’s claim 13 was as broad as construed by the district court, then it was invalid for “indefiniteness, lack of written description, non-enablement, anticipation, and obviousness.”⁵¹

The Supreme Court granted LabCorp.’s petition for certiorari on October 31, 2005.⁵² Of the three questions LabCorp. submitted for review, the only one the Court chose to address was:

“[w]hether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlate” test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result?”⁵³

This was a poorly written question from the perspective of patent law since it not only fails specifically to mention 35 U.S.C. §101, it also assumes its own answer. An “indefinite,” “undescribed,” and “non-enabling” method is, by definition, invalid under 35 U.S.C. §

46. U.S. Patent No. 4,940,658; Claim 13: “A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: “assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”

47. *Lab. Corp.*, 548 U.S. at 129.

48. *Id.* at 130.

49. *Id.*

50. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 370 F.3d 1354 (Fed. Cir. 2004).

51. *Lab. Corp.*, 548 U.S. at 130–31 (Breyer, J., dissenting).

52. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 546 U.S. 975, 975 (2005) (per curiam).

53. Petition for a Writ of Certiorari, *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, No. 04-607, 2004 WL 2505526, at *1 (U.S. filed Nov. 3, 2004).

112.⁵⁴ The case drew a large amount of attention from interested parties and industry groups who subsequently filed a considerable number of amicus briefs with the court.⁵⁵ Additionally, the Solicitor General of the United States submitted two briefs and participated in the oral arguments held on March 21, 2006.⁵⁶

On June 26, 2006, without further comment and without the then newly-installed Chief Justice Roberts participating, the Court dismissed the writ of certiorari in the *Lab. Corp.* case as improvidently granted.⁵⁷ Justice Breyer, joined by Justices Souter and Stevens dissented from the decision to dismiss.⁵⁸ Ostensibly, the reason for the dismissal lay in the fact that LabCorp. had not referred to patentable subject matter and 35 U.S.C. § 101 in either the district court proceedings nor in their arguments before the Federal Circuit regarding the invalidity of Metabolite's patent.⁵⁹ However, Justice Breyer, in his dissent, as well as many commentators regarded this rationale as tenuous, especially in light of the fully developed record on the matter before the Court provided by the multitude of amicus briefs.⁶⁰ In fact, the Court initially granted certiorari *in spite of* the

54. 1-1 Donald S. Chisum, *Chisum on Patents* § 1.03[2][e] (2010).

55. Amicus briefs filed in favor of LabCorp. included those from AARP, Affymetrix, Inc. and Professor John H. Barton, American Clinical Laboratory Association, American Heart Association, American Medical Association, the American College of Medical Genetics, the American College of Obstetricians and Gynecologists, the Association for Molecular Pathology, the Association of American Medical Colleges, and the College of American Pathologists, Patients not Patents, Inc., People's Medical Society, Public Patent Foundation; Amicus briefs filed in favor of Metabolite included those from American Intellectual Property Law Association, Boston Patent Law Association, Federal Circuit Bar Association, Franklin Pierce Law Center, Perlegen Sciences, Inc. and Mohr, Davidow Ventures.

56. Brief for the United States as Amicus Curiae, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, No. 04-607, 2005 WL 3533248 (U.S. filed Dec. 23, 2005); Brief for the United States as Amicus Curiae, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, No. 04-607, 2005 WL 2072283 (U.S. filed Aug. 26, 2005).

57. *Lab. Corp.*, 548 U.S. at 124 (per curium).

58. *Lab. Corp.*, 548 U.S. at 125 (Breyer, J., dissenting).

59. *Id.* at 132.

60. *Id.* at 132-33 (Breyer, J., dissenting); *see, e.g.*, Daniel T. Marvin, *The Supreme Court's Missed Opportunity to Settle the Handiwork of Nature Exception to Patentable Subject Matter in Laboratory Corporation of America v. Metabolite Laboratories*, 26 Temp. J. Sci. Tech. & Envtl. L. 113, 139 (2007) ("The record was adequately developed for the Court to render a decision on whether Claim 13 was patentable subject matter.") and John G. New, *Patently Wrong: The U.S. Supreme Court Punt in the Case of LabCorp v. Metabolite*, 10 Vand. J. Ent. & Tech. L. 147, 169 (2007) ("[U]nlike defenses mounted on issues of fact, which cannot be raised on appeal if they are not pled in the trial court, the validity of a patent based on the patentability of the subject matter under § 101 is a matter of law and may be reviewed *sua sponte* by the Court."); *see supra* note 56.

fact that in his initial brief on the matter, the Solicitor General recommended *against* deciding the question. Due to the numerous similar diagnostic patents already in existence, according to the Solicitor General, deciding to “overturn [the] PTO’s approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries.”⁶¹

On the merits, Justice Breyer strongly believed Metabolite’s claim 13 was invalid for lack of patentable subject matter under 35 U.S.C. § 101.⁶² Seeing “little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a ‘natural phenomenon,’”⁶³ he drew a strong comparison between Metabolite’s claim 13 and Morse’s claim 8 which had been invalidated by the Court a century and a half earlier.⁶⁴ Breyer greatly doubted whether the claim language even fit the traditional definition of a patentable “process,” as claim 13 merely “instructs the user to (1) obtain test results [by any means available] and (2) think about them.”⁶⁵ By Justice Breyer’s reckoning, a natural phenomenon does not suddenly become patentable under 35 U.S.C. § 101 if it is simply put in “process” form. That is, Einstein *still* could not patent the natural relationship between $E = mc^2$ by instructing the user to (1) measure the mass of something by any means available then multiply it by the speed of light squared and (2) think about the product of those numbers. Additionally, even assuming the claim language was, in fact, a patentable process, the claim amounted to nothing more than a simple correlation between serum homocysteine levels and the presence or absence of a disease.⁶⁶ Justice Breyer concluded that:

“[R]espondents have simply described the natural law at issue in the abstract patent language of a “process.” But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge [A]side from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an

61. Brief for the United States as Amicus Curiae, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, No. 04-607, 2005 WL 3533248, at *14 (U.S. filed Dec. 23, 2005).

62. *Lab. Corp.*, 548 U.S. at 135 (Breyer, J., dissenting).

63. *Id.*

64. *Id.* at 136–37; O’Reilly v. Morse, 56 U.S. at 112; *supra* note 28.

65. *Lab. Corp.*, 548 U.S. at 136 (Breyer, J., dissenting).

66. *Id.* at 137 (Breyer, J., dissenting).

unpatentable “natural phenomenon,” and I can find nothing in claim 13 that adds anything more of significance.”⁶⁷

Thus, the Supreme Court decided not to decide whether medical diagnostic methods were patentable. Rather, the Court let those types of patents remain valid, due to the lower Federal Circuit decision that did not even address the matter of patentable subject matter. Simultaneously, the Court cast great doubt on the validity of these types of patents due to Breyer’s dissent that was joined by one third of the Court. The next challenge to the patentability of medical diagnostics would not come from a case where the controversy was on point, but, rather, from the world of business method patents.

III. Judicial Interpretation of 35 U.S.C. §101 and the Uneasy Relationship between the Patentability of Business Methods and Diagnostic Medicine

A. The Mental Steps Doctrine and the Machine or Transformation Test

While becoming increasingly muddled by vague Federal Circuit and Supreme Court decisions throughout the years, the Mental Steps Doctrine generally states that “no patent can be obtained [under 35 U.S.C. § 101] for a method an essential component of which consists of human mental participation.”⁶⁸ The modern version of the Mental Steps Doctrine had its genesis in the Supreme Court’s 1972 decision in *Gottschalk v. Benson*.⁶⁹ In *Gottschalk*, the Court determined a method for converting numbers into binary numerals, which was useful in the programming of computers, was not patentable subject matter.⁷⁰ The reasoning Justice Douglas used to arrive at that conclusion, which Professor Chisum variously refers to as “illogical,” “uncertain,” “equivocal[],” and unable “to stand up under analysis,” seems to make two points relevant to the patentability of medical diagnostic and personalized medicine methods.⁷¹ First, “[a] method which can be performed mentally or which is the equivalent of human mental work is not patentable. Such methods are “basic tools”—

67. *Lab. Corp.*, 548 U.S. at 137–38 (Breyer, J., dissenting).

68. 1 Donald S. Chisum, *Chisum on Patents* § 1.03[6] (2003).

69. 409 U.S. 63 (1972).

70. *Id.* at 71.

71. 1 Donald S. Chisum, *Chisum on Patents* § 1.03 [6][c] (2003).

open to all.”⁷² Second, “[a] method which does not directly and physically alter or transform an article and which is not tied to the operation of a particular machine is not patentable.”⁷³ In *Lab. Corp.*, Breyer cited *Gottschalk*, to strengthen his argument that claim 13 was not patentable subject matter because it was (1) simply the mental process of measuring serum homocysteine and thinking about the results⁷⁴ and (2) not a method directed at the transformation of blood or anything else.⁷⁵

Six years later, the Supreme Court extended the doctrine set forth in *Gottschalk* when it decided, in a 6-3 decision, *Parker v. Flook*.⁷⁶ The patent at issue in *Flook* was for a method to update an “alarm limit” by taking variables such as temperature and pressure into consideration during catalytic conversion of hydrocarbons.⁷⁷ If one of the variables exceeded the mathematically calculated alarm limit, the system produced a signal indicating this fact.⁷⁸ The method consisted of three steps: (1) A measurement of a given variable followed by (2) a mathematical calculation to arrive at a new alarm limit value ending with (3) adjustment of the limit to correspond to that new value.⁷⁹ In ruling the method unpatentable subject matter, Justice Stevens held the fact that the mathematical algorithm of step (2) is followed by the “post solution activity” of step (3) is not enough to transform an unpatentable principle (the algorithm) into a patentable method.⁸⁰ Once stripped of the post-calculation

72. 1 Donald S. Chisum, *Chisum on Patents* § 1.03 [6][c] (2003).

73. *Id.*

74. *Lab. Corp.*, 548 U.S. at 127 (Breyer, J., dissenting).

75. *Id.* at 136.

76. 437 U.S. 584 (1978).

77. *Id.* at 585.

78. *Id.*

79. *Id.* at 596–97; *Flook*’s claim 1:

“ A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of Bo+K wherein Bo is the current alarm base and K is a predetermined alarm offset which comprises: (1) Determining the present value of said process variable, said present value being defined as PVL; (2) Determining a new alarm base B1, using the following equation: $B[1]=Bo(1.0<v1>minF)+PVL(F)$ where F is a predetermined number greater than zero and less than 1.0; (3) Determining an updated alarm limit which is defined as B1+GK; and thereafter (4) Adjusting said alarm limit to said updated alarm limit value.”

80. *Id.* at 590.

adjustment in step (3), the claimed method consists of nothing but the measurement of a variable followed by plugging that variable into an unpatentable mathematical formula. In *Lab. Corp.*, Stevens joined Breyer's dissent in comparing the diagnostic correlation at issue in that case with the rejected algorithm in *Flook*, determining that the subject matter at issue in both cases involved an unpatentable "simple natural correlation, *i.e.* a 'natural phenomenon.'"⁸¹

In Part III of the "Patent Eligibility Trilogy", the Court reversed course a bit in *Diamond v. Diehr* when, in a 5-4 decision authored by Justice Rehnquist, they determined a method for curing rubber incorporating an algorithm and a computer was patentable under 35 U.S.C. § 101.⁸² The method at issue in *Diehr* comprised (1) measuring the temperature in the rubber mold (2) calculation of the time required to cure the rubber via a specific mathematical equation, and (3) opening the rubber press when the calculated curing time passed.⁸³ The majority opinion carefully distinguished *Gottschalk* and *Flook*, which Rehnquist characterized as an attempt to patent a mathematical formula that produced binary code in the case of the former and a numerical alarm limit in the latter.⁸⁴ Rather than attempting to preempt the use of algorithms as in *Gottschalk* and *Flook*, *Diehr*'s claimed method:

"[d]escribe[s] in detail a step-by-step method for [transforming raw, uncured synthetic rubber into a different state or thing] with the loading of a mold with . . . uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. Industrial processes such as this are the type which have historically been eligible to receive the protection of our patent laws."⁸⁵

Consequently, under the reasoning of *Diehr*, the fact that a method claim incorporates a mathematical algorithm is not fatal to patentability as long as it is applied to a process that transforms a thing to a different state of being or requires some kind of a machine to carry out. This principle became the "Machine or Transformation Test." Justice Stevens vigorously dissented, arguing that the majority

81. *Lab. Corp.*, 548 U.S. at 137 (Breyer, J., dissenting).

82. 450 U.S. 175 (1981).

83. *Id.* at 179.

84. *Id.* at 185–86.

85. *Id.* at 184.

misinterpreted his earlier opinion in *Flook*⁸⁶ and contended Diehr's third step was the same type of "post solution activity" that failed to make *Flook*'s method patentable subject matter.⁸⁷

The Federal Circuit struggled for years to apply the principles of *Gottschalk*, *Flook*, and *Diehr* in cases involving claims to software and business methods. *State Street Bank & Trust Co. v. Signature Financial Group* involved "a data processing system . . . for implementing an investment structure which was developed for use in . . . business as an administrator and accounting agent for mutual funds."⁸⁸ The patent claimed a business method for pooling the assets of mutual funds into an investment portfolio organized as a partnership.⁸⁹ In an opinion by Judge Rich, a Federal Circuit panel reversed a district court ruling finding the patent did not fall into a class of patentable subject matter under 35 U.S.C. § 101.⁹⁰ While recalling the prohibition against patenting disembodied abstract mathematical algorithms as stated by the Supreme Court in *Gottschalk*, *Flook*, and *Diehr*,⁹¹ the panel held prior Federal Circuit precedent permitted the patenting of algorithms applied in useful ways to method claims.⁹² The court determined the data processing system was patentable because "the transformation of data . . . by a machine through a series of mathematical calculations . . . constitutes a practical application of a mathematical algorithm . . . because it produces 'a useful, concrete and tangible result.'"⁹³ This revelation, that an abstract or scientific principle only need be applied usefully under 35 U.S.C. § 101, was used by Metabolite in *Lab. Corp.* to argue that the diagnostic was patentable subject matter as it produced a useful, concrete, and tangible result: detection of B12 or folate deficiency.⁹⁴ However, Justice Breyer dismissed this argument in his dissent, remarking that while *State Street* "does say that a process is patentable if it produces a 'useful, concrete and tangible result' . . . this Court has never made such a statement and, if taken literally, the

86. 450 U.S. at 211 (Stevens, J., dissenting).

87. *Id.* at 215.

88. 149 F.3d 1368, 1370 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999).

89. *Id.*

90. *Id.*

91. *Id.* at 1373.

92. *Id.*; see *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (en banc); *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992).

93. *Id.* (citing *In re Alappat*, 33 F.3d at 1544) (emphasis added)

94. *Lab. Corp.*, 548 U.S. at 136 (Breyer, J., dissenting); see Brief for Respondents, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 2006 WL 303905, at *36–38.

statement would cover instances where this Court has held the contrary.”⁹⁵ Therefore, Breyer’s dissent in *Lab. Corp.* left patentees uncertain about not only the validity of correlative diagnostic patents, but also unsure of the continuing validity of the Federal Circuit’s holding in *State Street*. The stage for the next battle was set in motion when a gas utility employee from Pittsburgh, Pennsylvania named Bernard Bilski filed an application with the PTO in April of 1997.⁹⁶

B. In re Bilski: the Federal Circuit Decides to 'Put Up or Shut Up'

Bilski’s patent application claimed a method for hedging risks in the trading of various commodities.⁹⁷ Essentially, the method consisted of (1) initiating a series of sales between a broker and a purchaser where the purchaser buys the commodity at a fixed rate based on historical prices, (2) identifying the sellers or producers of the commodity, and (3) initiating a series of sales between the broker and the sellers/producers of the commodity at another fixed rate, so that the seller’s and purchaser’s respective risk balance one another.⁹⁸ In *Bilski*, the applicant was appealing a previous Board of Patent Appeals and Interferences decision rejecting the application as outside the scope of patentable subject matter under 35 U.S.C. § 101.⁹⁹ Following initial oral arguments but before final disposition of the case, the Federal Circuit, *sua sponte*, ordered en banc review and new oral arguments were heard on May 8, 2008.¹⁰⁰

The court began by characterizing Bilski’s claims as to a “process” and then defining a patentable “process” to exclude all

95. *Lab. Corp.*, 548 U.S. at 136 (Breyer, J., dissenting) (emphasis added).

96. U.S. Patent Application 08/833,892 (filed Apr. 10, 1997), *reprinted in* Petition for Writ of Certiorari app. at 10, *Bilski v. Doll*, 129 S. Ct. 2735 (U.S. Jan. 28, 2009) (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_Petitioner.pdf.

97. *In re Bilski*, 545 F.3d 943, 949 (Fed. Cir. 2008) (en banc).

98. U.S. Patent Application 08/833,892; Claim 1: A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of: (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer; (b) identifying market participants for said commodity having a counter-risk position to said consumers; and (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

99. *Ex parte Bilski*, Appeal No. 2002-2257, 2006 Pat. App. LEXIS 51, (B.P.A.I. 2006).

100. *In re Bilski*, 545 F.3d at 949.

“laws of nature, natural phenomena, [or] abstract ideas.”¹⁰¹ Next, the majority portrayed the “true issue[s]” in the case as whether or not *Bilski* sought “to claim a fundamental principle (such as an abstract idea) or a mental process” and to identify what test courts should use to differentiate between fundamental principles and patentable processes under 35 U.S.C. § 101.¹⁰² In defining the nature of the test, the court looked back to the principles elucidated by the Supreme Court in *Gottschalk*, *Flook*, and *Diehr*, and concluded the Machine or Transformation Test had *always* been the threshold inquiry for the determination of patentable subject matter: “A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”¹⁰³ In doing so, the Federal Circuit proclaimed the Machine or Transformation Test to be the *sole* test for patentability of processes under § 101 and disavowed any other measuring stick for these types of claims.¹⁰⁴ The court determined the claimed process at issue in *Gottschalk* was not, in fact, limited to computers (a machine) because the claimed algorithm was only useful in the context of computers and thus the applicant sought to preempt all uses of that algorithm (a fundamental principle).¹⁰⁵ Similarly, in *Flook*, the majority characterized the alarm limit calculation claim as unpatentable because it was neither tied to an apparatus or machine nor did it transform any matter from one state to another.¹⁰⁶ Finally, the court differentiated *Diehr* as passing both requirements of the Machine or Transformation Test as the claimed process at issue in that case was (1) tied to the rubber curing machine and (2) resulted in the transformation of rubber from an uncured to a cured state.¹⁰⁷

In affirming the primacy of the Machine or Transformation Test, the court had to deal with its earlier opinions in *State Street* and

101. *Bilski*, 545 F.3d at 952 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citing *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)); see *id.* at n.5, wherein the court defines “fundamental principles” to mean “laws of nature, natural phenomena, and abstract ideas”; Note also the Federal Circuit’s strong reliance on the definitions of “processes” as provided by *Diehr*, 450 U.S. at 185, *Flook*, 437 U.S. at 589, and *Gottschalk*, 409 U.S. at 67.

102. *Id.*

103. *Id.* at 954.

104. *Id.* at 956.

105. *Id.* at 955; see also *id.* at n.9 (discussing the *Bilski* court’s interpretation of the claim at issue in *Gottschalk*).

106. *Bilski*, 545 F.3d at 955; see also *id.* at n.8 (discussing the *Bilski* court’s interpretation of the claim at issue in *Flook*).

107. *Id.* at 954.

Alappat. The en banc panel noted that while “a process tied to a particular machine, or transforming or reducing a particular article into a different state or thing, will generally produce a ‘concrete’ and ‘tangible’ result . . . that inquiry is insufficient to determine whether a claim is patent-eligible under § 101.”¹⁰⁸ However, while certainly gutting the underlying rationale of the *State Street* decision, the *Bilski* court refused to completely overrule it and intimated that a business method may still be patentable subject matter *if* it conforms to the Machine or Transformation Test. This decision drew a vehement dissent from Judge Mayer who characterized *State Street* as having “led us down the wrong path” in approving the patentability of any business method at all.¹⁰⁹ Turning to the merits, the court determined in a 9-3 ruling that, while arguably useful, Bilski’s claimed method was neither tied to a machine nor resulted in the transformation of matter from one state to another and hence was unpatentable subject matter under the Machine or Transformation Test.¹¹⁰ Specifically, the majority noted:

“[T]he process as claimed encompasses the exchange of only options, which are simply legal rights to purchase some commodity at a given price in a given time period. The claim only refers to “transactions” involving the exchange of these legal rights at a “fixed rate corresponding to a risk position.” Thus, claim 1 does not involve the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance. Given its admitted failure to meet the machine implementation part of the test as well, the claim entirely fails the machine-or-transformation test and is not drawn to patent-eligible subject matter.”¹¹¹

Following the en banc court’s rejection of his application, Bilski petitioned the Supreme Court, which granted certiorari on June 1, 2009.¹¹²

108. *Bilski*, 545 F.3d at 959.

109. *Id.* at 1001 (Mayer J., dissenting).

110. *Id.* at 963–64.

111. *Id.* at 964.

112. *Bilski v. Doll*, 129 S. Ct. 2735 (U.S. Jun. 1, 2009) (No. 08-964) (mem.); the case was argued before the Supreme Court on Nov. 9, 2009 and renamed *Bilski v. Kappos* after David Kappos was appointed head of the PTO by President Obama (transcript available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/08-964.pdf (last visited May 8, 2010)).

It is important to put the Federal Circuit's decision in *Bilski* into context. Over the past few years, in several high profile cases, the Supreme Court made a habit of repudiating the Federal Circuit's patent jurisprudence as straying too far from Supreme Court precedent. This was vividly demonstrated in decisions such as *eBay Inc. v. MercExchange, L.L.C.*, where a unanimous Supreme Court determined the Federal Circuit's practice of automatically issuing an injunction following a finding of patent infringement was not in conformity with the Court's traditional four-factor test.¹¹³ Additionally, in *KSR Int'l Co. v. Teleflex, Inc.*, the Court unanimously ruled the Federal Circuit was applying its Teaching, Suggestion, and Motivation Test for the determination of obviousness under 35 U.S.C. §103 too rigidly based on the Court's prior decisions.¹¹⁴ An appreciation of this context places the majority's close reliance on the rationale of *Gottschalk, Flook*, and *Diehr* in declaring the Machine or Transformation Test to be the sole threshold inquiry under §101 into perspective. Additionally, Justice Breyer's thinly veiled criticism of *State Street's* "useful, concrete, or tangible result" language in *Lab. Corp.* may have helped push the majority to disavow adherence to that principle in determining patentable subject matter for processes.¹¹⁵ In fact, the *Bilski* majority opinion specifically mentions *Lab. Corp.* and characterizes the claim in that case as "similar" to *Bilski's* in that both "claim a non-transformative process that encompasses a purely mental process of performing requisite mathematical calculations without the aid of a computer or any other device."¹¹⁶ If the Supreme Court affirms the Federal Circuit's decision in *Bilski*, it will signal a seismic shift in the types of patents the PTO will grant while simultaneously calling into question the validity of hundreds of business method, medical diagnostic, and personalized medicine patents.

C. How Are Medical Diagnostic Method Patent Claims Currently Written?

As discussed, *supra*, restriction of patentable processes to subject matter conforming to the *Bilski* Court's Machine or Transformation Test may particularly impact diagnostic and personalized medicine

113. 547 U.S. 388, 390 (2006).

114. 550 U.S. 398, 415 (2007).

115. *Lab. Corp.*, 548 U.S. at 136 (Breyer J., dissenting); see *supra* note 96.

116. *Bilski*, 545 F.3d at 965; see also *id.* at n.27.

method patents. While it is possible the Supreme Court will limit the reach of *Bilski* and restrict it to business methods, it seems just as likely that processes neither tied to a machine nor able to change matter from one physical state to another will survive a broad general affirmation. The likelihood that these types of method patents will be declared invalid is particularly probable given that both the majority en banc Federal Circuit and Justice Breyer in his *Lab. Corp.* dissent seem to have serious reservations about the continued validity of methods like Metabolite's claim 13 for detecting B12 and folate deficiencies.¹¹⁷ Given this prospect, an analysis of issued diagnostic and personalized medicine method patents was conducted in order to get a general idea of the scope and nature of the effect that an affirmation of *Bilski* might have as well as to give patent agents and attorneys a better understanding as to how these types of claims are currently written.¹¹⁸

Clear patterns emerge in the construction of claims written for diagnostic and personalized medicine. All issued patents fell into one of four categories. The first category (I), was termed "*Lab. Corp.* claims" due to similarity to claim 13 at issue in *Lab. Corp. v. Metabolite, Inc.*. Essentially, these claims (1) test or assay a biomarker in a fluid or a tissue via a method that is well known in the art and then (2) correlate the results of that test/assay with a known standard to diagnose the pathology in question. Among the claims examined, 53% fell into this classification.¹¹⁹ The second category (II)

117. See *supra* notes 116–17.

118. The Delphion database was searched for issued patents using the keyword "biomarker" in the title and claim fields and "diagnose*" or "prognos*" in the claim field. After refining the initial search results to include only those patents relating to diagnostic and personalized medicine methods, a group of 32 issued patents was analyzed and is the subject of the summary *infra*. Note that the analyzed patent claims were not separated by patent families and the group may therefore include more than one patent from a given family depending on the wording of the claim. Nevertheless, multiple patents from the same families were included in the analysis due to the fact that each passed through prosecution and was allowed to issue by the PTO. Ordinals have been inserted into the representative claims, *infra*, where absent to provide for ease of reading.

119. See, e.g., Prediction of Prostate Cancer Progression by Analysis of Selected Predictive Parameters, U.S. Patent No. 6,025,128 (filed Sep. 29, 1994) (issued Feb. 15, 2000); Claim 1: A method of predicting prostate cancer progression, comprising: (a) obtaining prostate cells from a subject; (b) analyzing predictive parameters in the prostate cells, wherein the predictive parameters are nuclear morphometric descriptors, including: object sum optical density, picograms of DNA, contrast, correlation, sum average, sum variance, difference variance, difference entropy, information measure B, product moment, standard deviation, and DNA ploidy; and c) predicting cancer progression by statistical analysis of the predictive parameters, where the statistical analysis is logistic

of diagnostic and personalized medicine claims, called “biomarker identification,” included methods where an assay identifies a particular biomarker in a sample. The mere presence of the biomarker is indicative of disease. Among the claims examined, 23% fell into this classification.¹²⁰ The third category (III) had two independent claims in each instance. (1) The first claimed a computer-based system that a user trained to diagnose a disease state by inputting reference values for one or more biomarkers from a test population having subpopulations known to suffer from the diseases(s) in question. (2) A second independent claim was directed towards the method of using the system from the first independent claim to diagnose the disease. Of the claims examined, 15% fell into this category.¹²¹ Finally, the remaining 7% of these patent claims (IV) did not cleanly fall into any of the above three categories.

regression, discriminate analysis, recursive partitioning, neural network, or classification and regression tree analysis.

120. *See, e.g.*, Detection of Novel Carbohydrates Directly Associated with Chronic Alcoholism, U.S. Patent No. 5,747,346 (filed May 27, 1994) (issued May 5, 1998); Claim 31: A rapid and simple spot test method for diagnosing chronic alcoholism by detecting ethyl glucuronide, a biomarker whose presence in a fluid sample is specifically associated with chronic alcoholism, comprising the steps of: (a) obtaining a pre-determined volume of a sample from an individual being tested for the presence of ethyl glucuronide indicative of chronic alcohol consumption, wherein the sample is obtained at least 7 days after the individual has terminated alcohol consumption; (b) spotting the sample onto an absorbent substrate; (c) reacting the sample with a reagent comprising diphenylamine, aniline, and phosphoric acid or DAP reagent; and

(d) observing if there is a colorimetric reaction in the localized area of the spot, with the colorimetric reaction indicating the presence of alcohol-specific ethyl glucuronide in the sample, wherein the presence of ethyl glucuronide is diagnostic of chronic alcoholism; Claim 35: The method of claim 31, wherein in step (a) a pre-determined volume of a fluid sample from an individual who is a non-alcoholic and non-diabetic, and a pre-determined volume of a fluid sample containing ethyl glucuronide are provided as control samples, and further comprising the steps of: (e) spectrophotometrically measuring the amount of color observed in the localized spots of the test and control samples after (c); (f) comparing the spectrophotometric measurements to determine if the test sample contains the ethyl glucuronide.

121. *See, e.g.*, Computer Assisted Methods for Diagnosing Diseases, U.S. Patent No. 5,769,074 (filed May 3, 1996) (issued Jun. 23, 1998); Claim 1: A method for training a computer-based neural network to be used in diagnosing or prognosing disease in a patient comprising: preprocessing patient biomarkers, comprising: (a) selecting patient biomarkers associated with a disease process; (b) statistically and/or computationally testing discriminating power for indicating presence or absence of the disease of the selected patient biomarkers individually in linear and/or non-linear combination; (c) applying statistical, mathematical, or computational tools, and/or expert knowledge for the derivation of secondary input to the neural network that are linear or non-linear combinations of the original or transformed biomarkers; (d) selecting only those patient biomarkers or derived secondary inputs that show discriminating power; and (e) training the computer-based neural network using the preprocessed patient biomarkers or derived

D. Summary of the Current Patentability of Diagnostic and Personalized Medicine Method Claims

Evident from the analysis, *supra*, is the high percentage of claims (75%) appearing to fail the Machine or Transformation Test elucidated in *Bilski*. They all claim the measurement of biological samples via generalized and non-patented assays and biological techniques. Additionally, all of the claims in categories I and II appear to simply correlate the results of the measurement step with either a diagnostic standard (I) or the presence or absence of the biomarker itself (II) to determine the presence or absence of disease. None of the generalized claims of categories I or II appear to require the presence or operation of a machine or apparatus or result in the transformation of matter from one state to another. Rather, all of the claims in these two categories appear to claim a natural principle: the fact that certain biomarkers in human physiology either tend to modulate relative to known standards (I) or tend to disappear or appear in response to certain pathologies (II). These facts of nature have always existed independent of their later discoveries by scientists. These relationships are not “anything under the sun made by man” and it is difficult to see how they would fall into a classification of patentable subject matter under 35 U.S.C. § 101 if *Bilski* is affirmed.¹²²

On the other hand, those diagnostic claims utilizing the form of category III seem to require a machine for their function. Teaching a computer to recognize diagnostic markers in populations and then using that computer to recognize the probability of disease in individuals because of that teaching arguably conforms to the Machine or Transformation Test. Such diagnostic method claims may well survive a broad Supreme Court affirmation of *Bilski*. Given this probability, it may be in the interest of patent agents and attorneys to try to incorporate such computer-based methods into at least one of their patent claims for diagnostic and personalized medicine methods so as to meet the requirements of §101 as interpreted by the Machine or Transformation Test.

secondary inputs; Claim 2: A method for diagnosing or prognosing a disease in a patient, comprising: (a) introducing patient biomarkers into the trained computer-based neural network of claim 1; (b) receiving an output value from the computer-based neural network corresponding to the presence or the absence or the severity of the disease; and (c) transmitting the output value from the computer-based neural network to an output value receiver connected to a display means.

122. See *supra* note 13.

Some argue, in spite of the historical development of 35 U.S.C. § 101 and the reluctance to grant patents covering natural principles, judicial interpretation can successfully bend § 101's language to accommodate medical diagnostic and personalized medicine methods. A proponent of this is Judge Rader of the Federal Circuit, who in his *Bilski* dissent criticized both Breyer's "oft-discussed" dissent in *Lab. Corp.* and the *Bilski* majority's reliance upon it by noting:

"[t]he fundamental error in that *Lab Corp.* dissent is its failure to recognize the difference between a patent ineligible relationship—i.e., that between high homocysteine levels and folate and cobalamin [vitamin B12] deficiencies—and a patent eligible process for applying that relationship to achieve a useful, tangible, and concrete result—i.e., diagnosis of potentially fatal conditions in patients. Nothing abstract here. Moreover, testing blood for a dangerous condition is not a natural phenomenon, but a human invention. The distinction is simple but critical: A patient may suffer from the unpatentable phenomenon of nature, namely high homocysteine levels and low folate. But the invention does not attempt to claim that natural phenomenon. Instead the patent claims a process for assaying a patient's blood and then analyzing the results with a new process that detects the life-threatening condition. Moreover, the sick patient does not practice the patented invention. Instead the patent covers a process for testing blood that produces a useful, concrete, and tangible result: incontrovertible diagnostic evidence to save lives."¹²³

With all due respect to Judge Rader, it is he who commits a "fundamental error," not for the incorrect recognition of "the difference between a patent ineligible relationship . . . and a patent eligible process for applying that relationship" but for failing to recognize that, in the method at issue in *Lab. Corp.*, the patent ineligible relationship was *one in the same* with the process for applying that relationship.¹²⁴ The previously utilized example of Einstein's Theory of Relativity is instructive. The fact that energy (E) is equal to the mass of an object (m) times the speed of light (c) squared is a natural principle of physics, a fundamental law of nature that has always existed. The fact that serum homocysteine levels increase with Vitamin B12 and folate deficiencies is a natural

123. *Bilski*, 545 F.3d at 1014 (Rader J., dissenting).

124. *Id.*

principle of physiology, a fundamental law of human metabolism that has existed probably from the time humans evolved into omnivores. While it is true that “testing blood for a dangerous condition is not a natural phenomenon, but a human invention,” so too is it true that weighing an object to determine its mass (as in the “m” in $E = mc^2$) is not a natural phenomenon, but a human invention.¹²⁵ The problem with Rader’s logic is that, in performing the “process for assaying a patient’s blood and then analyzing the results with a new process that detects the life-threatening condition” a user simply applies the law of nature to a *specific* circumstance (i.e. that of the individual being tested).¹²⁶ Einstein’s theory does not become a patentable method simply because I claim use of the relationship by measuring the mass of a chair any more than if I perform it measuring the mass of an atom of hydrogen. In both cases I am simply restating the general natural principle but have substituted the mass of a real-world “thing” in the place of the variable “m.” So too in *Lab. Corp.*, analyzing a patient’s blood by a non-patentable technique (like weighing the mass of something in the Einstein example) and then plugging that variable into the equation (high serum homocysteine = vitamin deficiency) is merely *use of the natural principle to illustrate the natural principle*. They are one in the same.

This fact illustrates why the majority abandoned the “useful, concrete, and tangible result” language of *State Street*.¹²⁷ It was far too broad to keep natural principles out of patentable subject matter. As discussed *infra*, while there may be compelling public policy reasons to permit patents on these types of method claims, the static and relatively unchanging nature of the language of § 101 and interpretation of it by the courts, for better or for worse, simply will not permit this subject matter to pass the first hurdle for patentability.

IV. Should Diagnostic and Personalized Medicine Methods be Patentable Subject Matter?

As discussed, it is difficult to argue the statutory language and historical judicial interpretation of 35 U.S.C. § 101 permit the patenting of personalized medicine and general medical diagnostic method claims. Nevertheless, it is the purpose of this Note to argue granting these types of patents is not only in the public interest but

125. *Bilski*, 545 F.3d at 1014 (Rader J., dissenting).

126. *Id.*

127. See *supra* notes 112 and 119.

critical for the advancement of medical science. Judge Rader, while not convincing in his argument that the language of § 101 permits patenting of medical diagnostics like the one in *Lab. Corp.*, *supra*, nevertheless fully grasps the public policy implications of that lack of protection in his *Bilski* dissent. Rader accuses both the *Bilski* majority and Justice Breyer's *Lab. Corp.* dissent of "avoid[ing] the same fundamental question . . . : Is this entire field of subject matter undeserving of incentives for invention? If so, why?"¹²⁸ Judge Radar concisely notes that without the incentive of patent protection, the diagnostic test at issue in *Lab. Corp.* might still be unknown and people who develop vitamin B12 and folate deficiencies might still be subject to potentially life threatening medical conditions.¹²⁹ From a policy perspective, therefore, the problem with the *Bilski* majority and the dissent in *Lab. Corp.* is that if interpreted broadly they leave such critical medical advances unprotected and disincentivized "precisely because of [their] elegance and simplicity (the chief aims of all good science)."¹³⁰ This development threatens to inadvertently direct investor money away from the discovery of basic scientific relationships, like that of homocysteine relative to B12 deficiencies, that have a tangible and real impact on the lives of the public for earlier, cheaper, and more efficient diagnosis of "breast cancer or Lou Gehrig's disease or Parkinson's or whatever."¹³¹ It is the antithesis of the Constitutional mandate "[t]o promote the progress of science and useful arts."¹³²

Similarly, in her dissent from the majority decision in *Bilski*, Judge Newman notes "the full reach of today's change of law is not clear . . . Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed."¹³³ Newman further characterized the majority's ruling as "backward-looking" and a threat to the development of the economically critical, "rapidly moving[,] and commercially vibrant fields of the Information Age."¹³⁴ It is this threat to innovation, not just for the computer/software sector but also for the development of

128. *Bilski*, 545 F.3d at 1014 (Rader J., dissenting).

129. *Id.*

130. *Id.*

131. *Id.*

132. U.S. CONST. art. I, § 8, cl. 8; *see supra* note 3.

133. *Bilski*, 545 F.3d at 977 (Newman J., dissenting).

134. *Id.* at 992–93 (Newman J., dissenting)

new diagnostic and personalized medicine, which should be making policy experts and lawmakers nervous, not just for economic impact but for public health as well. The medical story of the early twentieth century was the essential eradication and prevention of communicable and, for the most part, early childhood diseases like polio, smallpox, measles, mumps, rubella, and tuberculosis. This had a huge effect on both human life expectancy and infant mortality in the United States and throughout the industrialized world.¹³⁵ Since more Americans are living longer relative to a century ago, it is now even more critical to develop quick, inexpensive, and basic diagnostic tools to catch conditions like cancer, heart disease, and diabetes early and at a stage where mortality rates are low with rapid and effective treatment. This absolutely vital need will be stymied and delayed without the full weight of the patent system behind it. Unfortunately, *Bilski* threatens to serve as an obstacle to this public health necessity, and either the Court or the Congress should prevent this from happening.

Some argue granting patents to these types of natural relationships will *impede* rather than encourage the development of new medical diagnostics and require patients to pay more to get the newest cutting edge diagnoses. For these individuals, no one should be forced to pay a licensing fee to find out whether or not they have a disease. The ACLU recently adopted this view and is currently participating in a lawsuit in the Southern District of New York to invalidate Myriad Genetic's patented test for genetic susceptibility to breast cancer via inherited mutations in the human BRCA1 and BRCA2 genes.¹³⁶ Additionally, these critics argue that granting patents on diagnostics such as the one in *Lab. Corp.* or Myriad's breast cancer test inhibits the developments of new technologies that will improve on the original tests.

Aside from the ACLU's unsubstantiated accusation that companies like Myriad are "patent[ing] DNA," these arguments do not stand up under legal or public policy analysis.¹³⁷ First, while it is

135. Dep't of Health & Human Services, Nat'l Ctr for Health Statistics; *Nat'l Vital Statistics Reports*, vol. 54, no. 19, June 28, 2006.

136. John Schwartz, *Cancer Patients Sue Testing Company and Government Over Gene Patents*, N.Y. TIMES, May 13, 2009, at A20.

137. *Id.*; A plaintiff in the case, Jan A. Nowak, president of the Association for Molecular Pathology declares "[y]ou can't patent my DNA, any more than you can patent my right arm, or patent my blood." However, Myriad has not patented *anyone's* DNA. Nor has Myriad "patented a gene." What Myriad has done, at great expense, is isolate and purify a human DNA sequence that represents a higher than normal probability for

true those wishing to use Metabolite or Myriad's test must pay a license fee for the right to do so, critics tend to overlook the fact that this is the *point* of the patent system. The Constitution clearly says the goal is to encourage progress in the sciences by securing for inventors "for *limited* times" the exclusive rights to their inventions.¹³⁸ The operative word here is "limited." Metabolite and Myriad's patents are not going to last forever. When they expire, anyone will be able to use the method as cheaply as possible. What critics like the ACLU and the Association for Molecular Pathology miss is the fact that without the incentive of a patent, we might not currently have *any* way to easily diagnosis vitamin B12 and folate deficiencies or predict the likelihood of developing breast and ovarian cancer. Critics should keep in mind that Myriad and the inventors of the test at issue in *Lab. Corp.* spent millions developing their diagnostic tools. It is unreasonable to suggest that they should be deprived of their ability to recoup that investment through a temporally-limited and constitutionally-mandated mechanism simply because the subject matter of the patent is a relationship between biological factors and a disease state. Certainly, no one would suggest that a method to diagnose cancer utilizing a new type of ultrasound machine is unpatentable subject matter because it involves identifying a biological factor (a tumor) and comparing its presence to the existence or absence of a disease state (cancer). Why is one patentable and the other not merely because the ultrasound example conforms to some arbitrary "Machine or Transformation Test?" Second, the notion that granting patents on these types of relationships impedes the improvement of these methods naively assumes that the diagnostic relationships at issue are the *only way* to achieve the diagnosis. Perhaps some other blood factor, besides homocysteine, indicates the presence of vitamin B12 or folate deficiency. Perhaps another DNA sequence or other biomarker, other than inherited mutations in BRCA 1 or 2, indicate a higher probability of developing breast cancer. Patents on these relationships will not impede but rather *encourage* the development of new and better diagnostic and personalized medical tests as

developing breast or ovarian cancer when present in a human being. In doing so, human DNA was combined with DNA from microorganisms such as bacteria to create a molecule that does not exist in nature and is *completely the work of human hands*. No one can "patent a gene" because a gene is a theoretical concept that represents how a sequence of DNA behaves in a certain cellular context. Saying Myriad has "patented a gene" is akin to saying that someone has "patented the Saint Bernard" or "the llama."

138. U.S. CONST. art. I, § 8, cl. 8 (emphasis added); *see supra* note 3.

inventors attempt to design around already patented methods. It is similar to assuming that the only way to improve transportation at the end of the nineteenth century was to make improvements on the steam engine while completely discounting the possibility that something like the internal combustion engine might be “out there.” Therefore, what follows are a couple of suggestions to ensure these types of medical methods remain patentable subject matter.

A. The Supreme Court Should Limit the Reach of the Bilski 'Machine or Transformation Test' to Restrict Only Business Method Patentability

In the Patent and Copyright Clause of the Constitution, the Framers resolved that the goal of the U.S. patent system should be towards the “promot[ion of] the progress of science and the useful arts.”¹³⁹ From the time of the late 18th Century and the writing of the Constitution, the term “useful arts” has evolved into what we now commonly refer to as “technology.”¹⁴⁰ In his dissenting opinion in *Bilski*, Judge Mayer notes that “by mandating that patents advance the useful arts, “[t]he Constitution explicitly limited patentability to . . . ‘the process today called technological innovation.’”¹⁴¹ Further, “the Supreme Court has repeatedly emphasized what renders subject matter patentable is ‘the application of the law of nature to a new and useful end.’”¹⁴² Mayer further argues “[m]ethods of doing business do not apply ‘the law of nature to a new and useful end.’ Because the innovative aspect of such methods is an entrepreneurial rather than a technological one, they should be deemed ineligible for patent protection.”¹⁴³ Consequently, Judge Mayer believes methods directed to social sciences such as economics, business, sociology, and psychology should be barred from patentability while at the same time new ways to apply natural principles should be granted patent protection.

The Supreme Court should follow the reasoning of Judge Mayer and affirm the Machine or Transformation Test in *Bilski* only to the

139. U.S. CONST. art. I, § 8, cl. 8; *see supra* note 3.

140. Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50, 54 (1949) (“The term ‘useful arts’ as used in the Constitution . . . is best represented in modern language by the word ‘technology.’”).

141. *Bilski*, 545 F.3d at 1001 (Mayer J., dissenting) (citing *In re Comiskey*, 499 F.3d 1365, 1375 (Fed. Cir. 2007)).

142. *Id.* at 1003 (Mayer J., dissenting) (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

143. *Id.*; *see also id.* at note 6.

extent that it renders business methods and other patents directed to the social sciences ineligible subject matter under 35 U.S.C § 101. A broad affirmation of the test with applicability to all method claims will not only throw the medical diagnostic and personalized medicine industries into chaos, but will reach into other areas vital to the economy as well, such as software and other computer-related technologies. Investors have relied on the patentability of these technologies and many small biotechnology companies could be wiped out overnight with an opinion that puts their main assets, i.e. their intellectual property, at risk for invalidity. Unlike Justice Breyer's dissent in *Lab. Corp.* and the majority en banc opinion in *Bilski*, the Supreme Court should carefully consider just how an affirmation of *Bilski* will effect what is essentially the last vibrant sector of the already troubled American economy and limit its reach accordingly.

A recent case decided by the Federal Circuit, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, seems to show the Federal Circuit wrestling with the Machine or Transformation Test in the context of medical diagnostic and personalized medicine patents.¹⁴⁴ In *Prometheus*, one of the claims at issue was for a method of determining drug metabolite concentrations in a patient following drug administration and using that data to adjust drug dosage to optimize efficacy and evade toxic side effects.¹⁴⁵ One thing readily apparent about claim 1 in *Prometheus* is its similarity to Metabolite's claim 13 in *Lab. Corp.* Both claims involve (1) determining the quantity of a single chemical in a bodily fluid and (2) using information about that chemical to deduce information about a different chemical in the bodily fluid.¹⁴⁶ In a decision no doubt bringing joy to nervous diagnostic biotechnology companies in the wake of *Bilski*, the Federal Circuit found that both the "administering the drug" and "determining the level" steps of the claimed method

144. 581 F.3d 1336 (Fed Cir 2009).

145. *Id.* at 1339–40; U.S. Patent No. 6,355,623 (filed March 12, 2002). Claim 1: A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8x10⁸ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

146. *Id.*; *supra* notes 47 and 146.

passed Machine or Transformation Test muster.¹⁴⁷ The result of *Prometheus*, therefore, seems to indicate the Federal Circuit's willingness to separate out business method claims from personalized medicine/diagnostic claims and give the latter their figurative stamp of approval in line with Judge Mayer's dissent in *Bilski*.¹⁴⁸ However, in spite of this apparent good news for the biotech industry, several important questions remain. Will the Supreme Court recognize the distinction between business methods and medical diagnostic patents that the Federal Circuit seems to see in the claims at issue in *Bilski* and *Prometheus*? Alternatively, will the Court broadly affirm the Machine or Transformation Test, subsequently leaving little room for diagnostic and personalized medicine claims? How will the full Court address Justice Breyer's dissent in *Lab. Corp.*? Given Justice Souter's recent retirement and the question mark that new Justice Sotomayor represents when it comes to patent issues, will Breyer's reasoning hold sway or will the conservatives on the Court rule differently? Finally, even if *Bilski* is affirmed, will the Supreme Court nevertheless grant certiorari in *Prometheus* so that it can decide the issue of diagnostic/personalized medicine patents directly and once and for all?

B. Congress Should Consider Creating a New Statutory Classification for the Protection of Diagnostic and Personalized Medicine Patents

The Supreme Court emphasizes lower courts "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress."¹⁴⁹ As detailed, *supra*, the words of the Patent Act, with regard to patentable subject matter, are essentially identical to the words approved by Congress in 1790.¹⁵⁰ Therefore, it is safe to assume that the first Congress did not "foresee" the importance of medical diagnostic and personalized medicine methods given the primitive state of medical knowledge at the time.¹⁵¹ Given this fact, Congress should amend the Patent Act to protect these important types of methods and to encourage individuals to pursue discovery of diagnostic relationships. Alternatively, Congress could create a separate classification of patent for diagnostic and personalized medicine. Such a move would not be unprecedented.

147. *Id.* at 1349–50.

148. *Supra* notes 142–44.

149. *Flook*, 437 U.S. at 596.

150. *See supra* notes 14, 17, 19–20.

151. *See supra* notes 22–24.

Prior to 1930, it was generally believed that plants were patent-ineligible subject matter because they were living things.¹⁵² When Congress passed the Townsend-Purnell Plant Patent Act in 1930, the United States became the first country to provide patent protection for plants.¹⁵³ The Constitution gives Congress sweeping authority to define patentable subject matter. It is in the public interest to encourage these types of patents to improve the health and lives of the citizenry.

A new patent regime for diagnostic and personalized medicine could also help relieve some of the fears of those opposed to granting property rights in these types of discoveries. The new system could limit the time-period of the patent grant, making it shorter than the 20 years given utility patents as is the case with the 14-year period granted for design patents.¹⁵⁴ Additionally, rather than starting the patent grant clock ticking on the date of application, this new regime could defer this until *after* a regulatory agency, such as the FDA, approves the diagnostic or personalized medical procedure for human use. Therefore, investors in these types of technologies will know exactly how long they have to recoup their investments, even if this is a shorter period than a regular utility grant. A system such as this would maintain innovation and investment into these types of life-saving technologies as well as facilitate faster movement into the public domain.

V. Conclusion

Medical diagnostic and personalized medicine patents have a long and contentious history in the PTO and with the courts. Thomas Jefferson's original Patent Act language survives today essentially unchanged from the time he penned it almost two and a quarter centuries ago. This text and the manner courts have interpreted it throughout the centuries seem to leave little room for the patentability of these technologies under 35 U.S.C. § 101. This is especially true in the wake of the Federal Circuit's en banc decision in *In re Bilski* and Justice Breyer's dissent in *Lab. Corp.* How the Supreme Court will rule in *Bilski* is anybody's guess. However, if the Court decides to affirm, it should carefully distinguish the

152. Max Stul Oppenheimer, *The "Reasonable Plant" Test: When Progress Outruns the Constitution*, 9 MINN. J.L. SCI. & TECH. 417, 417 (2008).

153. Townsend-Purnell Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. § 161 (2000)).

154. 35 U.S.C. § 173 (2000).

patentability of diagnostic and personalized medicine patents of the type at issue in *Lab. Corp.* and *Prometheus* from the business methods at issue in *Bilski* and *State Street Bank*. Alternatively, Congress should entertain extending special protection to these types of patents, as their continued existence is critical for the economy, public health, and quality of life in the United States.

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